Remarks

Claims 63-79, 81-108, 111-112 and 117-121 are now pending in this application.

The Examiner noted that Applicant's amendment mailed March 15, 2005 fails to comply with the provisions of 37 CFR 1.121. In particular, the Examiner stated that the status identifiers for claims 96 and 97 are improper and incorrect. Applicant thanks the Examiner for bringing this to Applicant's attention. Applicant has corrected the status identifiers for claims 96 and 97 herein.

The 35 U.S.C. § 103(a) Rejection of the Claims

The Examiner rejected claims 63-79, 81-108, 111-112 and 117-121 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Szycher et al. ('627) or WO 98/13405 or JP 4-248826, each in view of Li et al. ('724) and Ohtaki et al. ('805). This rejection is respectfully traversed.

The Examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. If the Examiner does not establish a *prima facie* case, the Applicant is under no obligation to submit evidence of non-obviousness. M.P.E.P. §2142. To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves, or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all of the claim limitations. M.P.E.P. §2142.

In the Office Action the Examiner conceded that none of the primary documents (Szycher '627, WO 98/13405, and JP 4-248826) "disclose the specific use of an amine functional siloxane as a chain extender and WO 98/13405 fails to disclose the use of an amine functional siloxane soft segment" (Official Action, page 3). However, the Examiner asserts that Li et al. '724 disclose the use of amine functional polysiloxane compounds which overlap Applicants' claimed soft and hard segment compounds in the production of biocompatible polyureas and polyurethane-ureas. In addition, the Examiner asserts that Ohtaki discloses amino functional tetraoganodisiloxanes as reactants with polyurethanes.

Szycher et al. U.S. 5,863,627 (the '627 patent): as noted above, the Examiner acknowledges that there is no mention of the use of amine functional siloxanes as chain extenders in the '627 patent. The chain extenders disclosed are short diamines of diols (See column 4, lines 59-67.), *i.e.*, non-siloxanes, conventional in the polyurethane art. As discussed above, the use of a bis-amine terminated siloxane as a chain extender in the hard segment as well as in the soft segment of the claimed polyurethane urea structure is not disclosed or suggested in the disclosure of the '627 patent. With respect to claim 104, the use of a low molecular weight bis-amine terminated bis- to tetra- siloxane in the hard segment is also not disclosed or suggested by Szycher et al.

JP 4-248826 (abstract): Based on the information in the abstract, the amine functional siloxanes disclosed are used only in the soft segment in these formulations and not as a component in the hard segment. Again, this document fails to disclose the use of a amine functional siloxanes both as a chain extender and as a soft segment component of a polyurethane urea.

WO 98/13405: This commonly-assigned document also fails to disclose the use of amine functional siloxanes as chain extenders in the hard segment (claims 104). Furthermore, there is no teaching or suggestion of the use of bis-amine terminated siloxanes in both the hard and soft segments of polyurethanes as recited by claim 1.

Li et al. U.S. 5,221,724 (the '724 patent): The '724 patent discloses soft segments formed from a diisocyanate and a bis-amine terminated siloxane having 2-201 silicon atoms. Hard segments are formed from chain extended diisocyanates using conventional alkyl- or aryl-diols, or alkyl- or aryl-diamines as chain extenders. However, there is no teaching or suggestion to use amine terminated siloxanes of selected molecular weights to form both soft and hard segment components within the same polyurethane structure or to use bis-amine terminated disiloxane which contains 1-4 silicon atoms in the hard segment. Thus, the '724 patent does not cure the deficiencies of any of the primary references and would not permit one to arrive at the claimed compositions.

Ohtaki *et al.* U.S. 5,861,085 (the '085 patent): This document discloses the use of amino functional tetraorganodisiloxane as a modifier for polyurethanes. However, there is no teaching or suggestion to use the amino functional disiloxanes in both the hard and soft segments of any

polyurethane, or to use it only in the hard segement. Similarly, the '085 patent of fails to cure or complete the deficiency of any of the primary documents and would not permit one to arrive at the claimed compositions.

Accordingly, none of the cited documents {Szycher '627, WO 98/13405, or JP 4-248826; each in view of Li '724 and Ohtaki '085}, alone or in any combination, disclose or suggest all of the elements of the presently claimed invention. Specifically, none of these documents disclose or suggest the use of a amine functional siloxane compound of formula (I) wherein n = 1 to 4 as a chain extender in the hard segment, as in compositions of the present claims. Additionally, none of these documents disclose or suggest polyurethane-urea compositions where both the soft segment and the hard segment contain silicone-containing macrodiamine compounds (n = 5 to 100 and n = 1-4) as claimed in the present claims. It is respectfully submitted that the Examiner is employing hindsight to arrive at Applicant's invention by assembling it from isolated disclosures in the art. Without knowledge of Applicant's invention, there would be no motivation to use bis-amino terminated siloxanes disclosed in the secondary references to arrive at the claimed polyurethanes.

In particular, the Examiner's attention is directed to Example 1 which discloses a polyurethane urea consisting of amine functional siloxane segments forming both hard and soft segment components and having a high tear strength. The Examiner's attention is also directed to Example 13 where the results of a sheep implant study exhibit the biostability and fatigue resistance of the polyurethane ureas of the present invention. Finally, Example 14 provides data on cyclic flex fatigue resistance which further illustrates the excellent fatigue resistance of the polyurethane ureas of the present invention. Applicants respectfully submit that these examples illustrate the unexpected advantages of the claimed polymers prepared using amine functional siloxanes in both the soft and hard segments to improve tear strength as well as fatigue resistance is not obvious from the cited references.

Even assuming, arguendo, that one of skill in the art in possession of the cited art would be motivated to prepare Applicants' polyurethane-urea elastomeric composition, the Examiner is respectfully reminded that if a composition has unique and unexpected properties, and there is nothing in the prior art to indicate that the composition would have such properties, the

composition is not obvious in view of the prior art. In re Papesch, 315 F.2d 381, 137 U.S.P.Q. 43 (C.C.P.A. 1963); In re Lunsford, 148 U.S.P.Q. 716 (C.C.P.A. 1966).

To rebut a *prima facie* case of obviousness, Applicants can submit evidence of unexpected results in the form of an affidavit or declaration under 37 C.F.R. §1.132. M.P.E.P. §716.02 (e), citing In re Burckel, 201 U.S.P.Q. 67 (C.C.P.A. 1979). The evidence relied upon by Applicants to establish unexpected results should demonstrate " 'that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance.' " Id., citing Ex parte Gelles, 22 U.S.P.Q.2d 1318, 1319 (B.P.A I. 1992). Evidence of unexpected properties may be in the form of a direct or an indirect comparison of the claimed invention with the closest prior art which is commensurate in scope with the claims. M.P.E.P. §716.02(b).

As evidence that Applicants' invention possesses unexpected properties, the Examiner is requested to consider the enclosed Declaration of Pathiraja Arachichillage Gunatillake, who is a named co-inventor on the present application. In the Declaration, Pathiraja Arachichillage Gunatillake discusses the comparison of polymers of Example 1 of the instant specification to representative polymers of WO 98/13405 and Li et al. and concludes that the presently claimed polymers exhibit unexpectedly improved properties over those exemplified in the references.

Accordingly, it is respectfully submitted that the claimed invention is not obvious over the cited documents taken alone or in an combination. Applicants respectfully request withdrawal of the rejection of the present claims under 35 U.S.C. § 103(a).

Therefore, Applicant respectfully requests the Examiner to withdraw the rejections under 35 U.S.C. § 103(a).

Conclusion

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney at (612) 373-6905 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

PATHIRAJA A. GUNATILLAKE ET AL.

By their Representatives,

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. Box 2938
Minneapolis, MN 55402
(612) 373-6905

Date July 6, 2006

By Monique M. Perdok Shonka
Monique M. Perdok Shonka
Reg. No. 42,989

Date of Deposit: July 6, 2006
This paper or fee is being filed on the date indicated above using the USPTO's electronic filing system EFS-Web, and is addressed to: MS RCE, The Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

CANDIS BUENDING
Name

Signature